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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,908	07/31/2000	Jason A. Kay	Kay 41-53-18-79-12	5021

7590 11/04/2002  
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EXAMINER

HOFFMANN, JOHN M


ART UNIT	PAPER NUMBER
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1731

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DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/628,908	Applicant(s) KAY ET AL. 	
	Examiner John Hoffmann	Art Unit 1731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 12-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-15, 22 and 23 is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

09/628,908

## DETAILED ACTION

### *Drawings*

The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. 37 CFR 1.83(b) reads as follows:

When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The new formal drawing show the device in such a manner that one of ordinary skill could not understand the invention because it would not work as shown. Name the arms 24a and 24b could not physically pivot - because there is no clearance near the pivot points 25. The base of the arms are fully abut the tube 27.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 16-21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At least claims 1,3,5,7 and 19 have newly added language "at least one of...." It is unclear what such limitations require. It appears that they might be intended to be Markush groups - however the courts have consistently held that Markush groups be of a limited group - such as "at least member of the group consisting of". For example, the claim 1 language of "wherein said insertion device includes at least one of a sleeve and a handle" could be interpreted as "at least one of member of the group consisting of a sleeve and a handle", or "at least one of member of the group comprising a sleeve and a handle," or even "at least one sleeve and at least one handle." One of ordinary skill would be unable to tell how to interpret these limitations. The list of claims with such improper language (i.e. "at least one of...") is not intended to be exhaustive - the burden is on Applicant to correct all such defective language.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Doty 3293018.

Looking to the Doty figures (in particular 1 and 7): 13 and/or 17 is the support device. 15 is the heat source. 28 is the internal mold. The (unnumbered) hand-wheel on feature 14 is deemed to be the "insertion device" - it is deemed that this handwheel is a handle. Alternatively, the phrase "wherein said insertion device includes at least one of a sleeve and a handle" is unclear to its meaning; see the above 112 rejection which lists three different interpretations. The Office gives claims their broadest reasonable interpretation. The broadest of the three interpretations is "at least one of a group comprising a sleeve and a handle"; this group is open to any other member including a handwheel - or what ever structure is used in Doty to insert the mold.

Feature 23 is the "exterior molding device": looking to the sentence spanning pages 11-12; it is deemed that this "means" can be a "paddle" and that Doty's 23 is a "paddle". AS to the method of use limitations that indicate as to how the exterior molding device function: the Doty apparatus can be used in such a manner. Although Doty uses the device to expand the preform outwardly, it could also be used to compress another preform inwardly.

Claim 5: see figure 2, feature 23.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Zauner 3257186.

See features 22, 23, 28 and 27 of figure 1 and the associated text of Zauner. It is deemed that any structure that can be gripped by one's hand is a "handle".

Claims 1-5, 7-8 and 16-17, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Zauner 4441908.

See figures 8 and 10. 46 and/or 16 comprise the support device. 308 are the internal mold and 276 points to one of the outer mold. The paragraph spanning cols. 8-9 discloses that the operation is of the device in the same manner as Applicant claims their invention. Various structure could be considered to be the "insertion device", for example structure 220. It is inherent that there is a heat source.

Claim 8: figure 2, feature 44 is the activation device that sets the internal mold as claimed - via the camming action of features 212 and 224 (fig. 8).

Claim 16: it is clear that one could set a tube inside the Zauner tube.

Claim 1 is met for substantially the same reason claim 7 is met. As to the language that the insertion device is for inserting the mold "prior to the application of heat". Application of heat is a method of use step which does not have much (if any) bearing on the structure. It is clear that one can apply heat to the tube - well after the final device is made - even if Zauner does not disclose it.

Claim 2 is clearly met.

Claim 3: figure 2, feature 44 is the activation device that sets the internal mold as claimed - via the camming action of features 212 and 224 (fig. 8).

Claim 4 is clearly met.

Claim 5 is clearly met as per the above description.

Claim 17: the Zauner device is a lathe in as much as Applicant's device is. Applicant's support device is merely the chuck (work piece holder) of a lathe. In as Applicant's chuck is a lathe, Zauner's chuck is a lathe.

Claim 19 is clearly met.

Claim 20 requires setting the open configuration of the mold before and during a period in which heat is applied. First it is noted that the Zauner apparatus makes vials on a continuous basis. Each mold opens and closes as the turntable 42 makes it circuit. Clearly heat is applied many times ( see col. 2, line 2 for instance). It is clear that for a given station there would be a first opening/closing of the Zauner inner mold on the first pass, and a second opening/closing on the second, etc. Thus the first opening/closing is "before" the heating that corresponds to the second opening/closing. Also, the second opening/closing is "during a period in which heat is applied" i.e. the second heating. It is noted that the claim does not limit the period, nor the heating in any manner. Thus one can choose any time period (for example, 1 year) in which heat is applied - for at least a portion of the period. It is clear that one could arbitrarily choose a time period which includes heating and includes the second opening - so that the second opening occurs during that period which includes the heat application.

Claim 21 is clearly met - because the invention would not work if the end is not malleable.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zauner 4441908

It would have been obvious to completely automate the Zauner process/apparatus so that it makes the tubes automatically - because it would be cheaper than having a person do it. It would have been further obvious to use optical imaging to check the final product to make sure that the final product is not defective.

### ***Allowable Subject Matter***

Claims 12-15 and 22-23 are allowed.

### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

It is argued that Doty does not have the "features" of a sleeve and a handle. As indicated above, the broadest reasonable interpretation does not require both of these features.

It is also argued that Zauner'908 does not have an open and extended configuration and a closed and collapsed configuration. The rejection points to the



relevant portions of the reference. Furthermore, if the two inner mold members (308) do not collapse, then they could never be removed from the vial - the drawing clearly shows that an inside lip would be made inside the vials that would prevent the withdrawal of members 308.

### ***Conclusion***

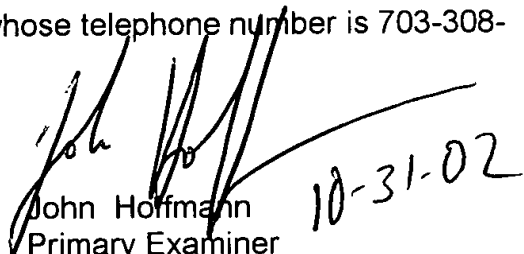
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Hoffmann whose telephone number is 703-308-0469. The examiner can normally be reached on Monday through Friday, 7:00- 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steve Griffin can be reached on 703-308-1164. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7115 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

  
John Hoffmann  
Primary Examiner  
Art Unit 1731  
10-31-02

jmh  
October 30, 2002